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**Introduced by Senator Chesbro**February 23, 1999

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An act to amend Section 1206.5 of the Business and Professions Code, relating to clinical laboratories.

## LEGISLATIVE COUNSEL'S DIGEST

SB 585, as introduced, Chesbro. Clinical laboratories.

Existing law provides that clinical laboratory examinations classified as physician-performed microscopy under specified federal regulations governing clinical laboratories may be performed by licensed physicians and surgeons, as specified.

This bill would expand that category of persons who may perform those clinical laboratory examinations to include licensed nurse practitioners, licensed physician's assistants, licensed nurse midwives, and licensed dentists. The bill would also make technical changes.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 1206.5 of the Business and  
2 Professions Code is amended to read:  
3 1206.5. (a) Notwithstanding subdivision (b) of  
4 Section 1206, no person shall perform a clinical laboratory  
5 test or examination classified as waived under CLIA  
6 unless the clinical laboratory test or examination is  
7 performed under the overall operation and  
8 administration of the laboratory director, as described in



1 Section 1209, including, but not limited to,  
2 documentation by the laboratory director of the  
3 adequacy of the qualifications and competency of the  
4 personnel, and the test is performed by any of the  
5 following persons:

6 (1) A licensed physician and surgeon holding a M.D. or  
7 D.O. degree.

8 (2) A licensed podiatrist or a licensed dentist when the  
9 results of the tests can be lawfully utilized within his or  
10 her practice.

11 (3) A person licensed under this chapter to engage in  
12 clinical laboratory practice or to direct a clinical  
13 laboratory.

14 (4) A person authorized to perform tests pursuant to  
15 a certificate issued under ~~Chapter 7 (commencing with~~  
16 ~~Section 1000) of Part 2 of Division 1 Article 5~~  
17 ~~(commencing with Section 101150) of Chapter 2 of Part~~  
18 ~~3 of Division 101 of the Health and Safety Code.~~

19 (5) A licensed physician assistant when authorized by  
20 a supervising physician and surgeon in accordance with  
21 Section 3502 or Section 3535.

22 (6) A person licensed under Chapter 6 (commencing  
23 with Section 2700).

24 (7) A person licensed under Chapter 6.5  
25 (commencing with Section 2840).

26 (8) A perfusionist when authorized by and performed  
27 in compliance with Section 2590.

28 (9) A respiratory care practitioner when authorized  
29 by and performed in compliance with Chapter 8.3  
30 (commencing with Section 3700).

31 (10) A medical assistant, as defined in Section 2069,  
32 when the waived test is performed pursuant to a specific  
33 authorization meeting the requirements of Section 2069.

34 (11) A pharmacist, when ordering drug  
35 therapy-related laboratory tests in compliance with  
36 ~~subparagraph (B) of paragraph (4) of, or clause (ii) of~~  
37 ~~subparagraph (A) of paragraph (5) of, subdivision (c) of~~  
38 ~~Section 4046 clause (ii) of subparagraph (A) of paragraph~~  
39 ~~(5) of subdivision (a) of, or paragraph (6) of subdivision~~  
40 ~~(a) of, Section 4052.~~

1 (12) Other health care personnel providing direct  
2 patient care.

3 (b) Notwithstanding subdivision (b) of Section 1206,  
4 no person shall perform clinical laboratory tests or  
5 examinations classified as of moderate complexity under  
6 CLIA unless the clinical laboratory test or examination is  
7 performed under the overall operation and  
8 administration of the laboratory director, as described in  
9 Section 1209, including, but not limited to,  
10 documentation by the laboratory director of the  
11 adequacy of the qualifications and competency of the  
12 personnel, and the test is performed by any of the  
13 following persons:

14 (1) A licensed physician and surgeon holding a M.D. or  
15 ~~D.O.~~ D.O. degree.

16 (2) A licensed podiatrist or a licensed dentist when the  
17 results of the tests can be lawfully utilized within his or  
18 her practice.

19 (3) A person licensed under this chapter to engage in  
20 clinical laboratory practice or to direct a clinical  
21 laboratory.

22 (4) A person authorized to perform tests pursuant to  
23 a certificate issued under ~~Chapter 7 (commencing with~~  
24 ~~Section 1000) of Part 2 of Division 1 Article 5~~  
25 ~~(commencing with Section 101150) of Chapter 2 of Part~~  
26 ~~3 of Division 101~~ of the Health and Safety Code.

27 (5) A licensed physician assistant when authorized by  
28 a supervising physician and surgeon in accordance with  
29 Section 3502 or Section 3535.

30 (6) A person licensed under Chapter 6 (commencing  
31 with Section 2700).

32 (7) A perfusionist when authorized by and performed  
33 in compliance with Section 2590.

34 (8) A respiratory care practitioner when authorized  
35 by and performed in compliance with Chapter 8.3  
36 (commencing with Section 3700).

37 (9) A person performing nuclear medicine technology  
38 when authorized by and performed in compliance with  
39 ~~Chapter 7.2 (commencing with Section 25625) of~~  
40 ~~Division 20 Article 6 (commencing with Section 107115)~~

1 *of Chapter 4 of Part 1 of Division 104 of the Health and*  
2 *Safety Code.*

3 (10) Any person when performing blood gas analysis  
4 in compliance with Section 1245.

5 (11) (A) A person certified as an “Emergency  
6 Medical Technician II” or paramedic pursuant to  
7 Division 2.5 (commencing with Section 1797) of the  
8 Health and Safety Code while providing prehospital  
9 medical care, a person licensed as a psychiatric technician  
10 under Chapter 10 (commencing with Section 4500) of  
11 Division 2, as a vocational nurse pursuant to Chapter 6.5  
12 (commencing with Section 2840) of Division 2, or as a  
13 midwife licensed pursuant to Article 24 (commencing  
14 with Section 2505) of Chapter 5 of Division 2, or certified  
15 by the department pursuant to Division 5 (commencing  
16 with Section 70001) of Title 22 of the California Code of  
17 Regulations as a nurse assistant or a home health aide,  
18 who provides direct patient care, so long as the person is  
19 performing the test as an adjunct to the provision of  
20 direct patient care by the person, is utilizing a  
21 point-of-care laboratory testing device at a site for which  
22 a laboratory license or registration has been issued, meets  
23 the minimum clinical laboratory education, training, and  
24 experience requirements set forth in regulations adopted  
25 by the department, and has demonstrated to the  
26 satisfaction of the laboratory director that he or she is  
27 competent in the operation of the point-of-care  
28 laboratory testing device for each analyte to be reported.

29 (B) Prior to being authorized by the laboratory  
30 director to perform laboratory tests or examinations,  
31 testing personnel identified in subparagraph (A) shall  
32 participate in a preceptor program until they are able to  
33 perform the clinical laboratory tests or examinations  
34 authorized in this section with results that are deemed  
35 accurate and skills that are deemed competent by the  
36 preceptor. For the purposes of this section, a “preceptor  
37 program” means an organized system that meets  
38 regulatory requirements in which a preceptor provides  
39 and documents personal observation and critical

1 evaluation, including review of accuracy, reliability, and  
2 validity, of laboratory testing performed.

3 (12) Any other person within a physician office  
4 laboratory when the test is performed under the  
5 supervision of the patient's physician and surgeon or  
6 podiatrist who shall be accessible to the laboratory to  
7 provide onsite, telephone, or electronic consultation as  
8 needed, and shall: (A) ensure that the person is  
9 performing test methods as required for accurate and  
10 reliable tests; and (B) have personal knowledge of the  
11 results of the clinical laboratory testing or examination  
12 performed by that person before the test results are  
13 reported from the laboratory.

14 (13) A pharmacist, when ordering drug  
15 therapy-related laboratory tests in compliance with  
16 ~~subparagraph (B) of paragraph (4) of, or clause (ii) of~~  
17 ~~subparagraph (A) of paragraph (5) of, subdivision (c) of~~  
18 ~~Section 4046~~ *clause (ii) of subparagraph (A) of paragraph*  
19 *(5) of subdivision (a) of, or paragraph (6) of subdivision*  
20 *(a) of, Section 4052.*

21 (c) Notwithstanding subdivision (b) of Section 1206,  
22 no person shall perform clinical laboratory tests or  
23 examinations classified as of high complexity under CLIA  
24 unless the clinical laboratory test or examination is  
25 performed under the overall operation and  
26 administration of the laboratory director, as described in  
27 Section 1209, including, but not limited to,  
28 documentation by the laboratory director of the  
29 adequacy of the qualifications and competency of the  
30 personnel, and the test is performed by any of the  
31 following persons:

32 (1) A licensed physician and surgeon holding a M.D. or  
33 D.O. degree.

34 (2) A licensed podiatrist or a licensed dentist when the  
35 results of the tests can be lawfully utilized within his or  
36 her practice.

37 (3) A person licensed under this chapter to engage in  
38 clinical laboratory practice or to direct a clinical  
39 laboratory when the test or examination is within a

1 specialty or subspecialty authorized by the person's  
2 licensure.

3 (4) A person authorized to perform tests pursuant to  
4 a certificate issued under ~~Chapter 7 (commencing with~~  
5 ~~Section 1000) of Part 2 of Division 1 Article 5~~  
6 ~~(commencing with Section 101150) of Chapter 2 of Part~~  
7 ~~3 of Division 101~~ of the Health and Safety Code when the  
8 test or examination is within a specialty or subspecialty  
9 authorized by the person's certification.

10 (5) A licensed physician assistant when authorized by  
11 a supervising physician and surgeon in accordance with  
12 Section 3502 or Section 3535.

13 (6) A perfusionist when authorized by and performed  
14 in compliance with Section 2590.

15 (7) A respiratory care practitioner when authorized  
16 by and performed in compliance with Chapter 8.3  
17 (commencing with Section 3700).

18 (8) A person performing nuclear medicine technology  
19 when authorized by and performed in compliance with  
20 ~~Chapter 7.2 (commencing with Section 25625) of~~  
21 ~~Division 20 Article 6 (commencing with Section 107115)~~  
22 ~~of Chapter 4 of Part 1 of Division 104~~ of the Health and  
23 Safety Code.

24 (9) Any person when performing blood gas analysis in  
25 compliance with Section 1245.

26 (10) Any other person within a physician office  
27 laboratory when the test is performed under the onsite  
28 supervision of the patient's physician and surgeon or  
29 podiatrist who shall: (A) ensure that the person is  
30 performing test methods as required for accurate and  
31 reliable tests; and (B) have personal knowledge of the  
32 results of clinical laboratory testing or examination  
33 performed by that person before the test results are  
34 reported from the laboratory.

35 (d) Clinical laboratory examinations classified as  
36 ~~physician-performed~~ *provider-performed* microscopy  
37 under CLIA may be performed by a licensed physician  
38 and surgeon holding a M.D. or D.O. degree, *a licensed*



- 1 *nurse practitioner, a licensed physician's assistant, a*
- 2 *licensed nurse midwife, or a licensed dentist.*

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